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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,979	03/24/2004	Assaf Govari	BIO-5044	4469

27777 7590 04/19/2007  
PHILIP S. JOHNSON  
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NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/807,979

Applicant(s)

GOVARI, ASSAF

Examiner

Peter J. Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The application is published application number: 2005/0215 990. The publication is classified in US 606/27.

The effective filing date of this application is 3-24-04.

Pending claims are 1 and 4-11.

Finality is withdrawn in light of newly found art. Shturman (5,331,947) clearly discloses a catheter comprising 32/64 ultrasound transducers positioned cylindrically (corresponding with a range of azimuths between 180 and 359 degrees). See column 6:45-52. (The dispositive issue in the Appeal Brief dated 12-21-06 appears to be that the prior art was silent regarding 32/64 ultrasound transducers capable of emitting energy in a range of azimuths between 180 and 359 degrees.)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1 and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa (6,971,394) in view of Shturman (5,331,947).**

Sliwa discloses numerous embodiments including a catheter with ablation devices (see figures 5a-c, 12-13, 14a). It is noted that Sliwa discloses that ablation

devices can be electrodes or ultrasonic transducers (col. 3:7-14). Therefore, disclosed embodiments with electrodes are tantamount to disclosing the same embodiment but with ultrasound transducers.

In another embodiment including an ablation device (see figure 64) Sliwa discloses:

1. Apparatus (see figure 64, *inter alia*) for use with a subject, comprising: a catheter (see figure 8, *inter alia*) having a longitudinal axis and having a distal portion; and an ultrasound array (406) fixed to the distal portion, adapted to operate in a phased array mode (col. 29:26-30) to apply ablating energy to tissue of the subject. **Further**, Sliwa discloses an apparatus wherein an ultrasound array is adapted to apply the ablating energy to tissue in a range of azimuths between about 180 and 359 degrees (Sliwa discloses an apparatus for forming a **continuous lesion around the circular pulmonary vein** – see col. 3:10-15).

4. The apparatus according to claim 1, wherein when the catheter is disposed in a vicinity of an ostium of a pulmonary vein (col. 2:57-60, *inter alia*) of the subject, the range of azimuths is sufficiently smaller than 360 degrees to avoid inducing a deficit in a phrenic nerve (col. 17:25-30; col. 2:22) of the subject.

5. The apparatus according to claim 1, comprising detection functionality (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51), adapted to determine tissue of the subject that is not to be targeted by the ablating energy

(visualization / imaging certainly does this), wherein the ultrasound array is adapted to (control system 334; col. 34:45-57) configure the ablating energy responsive to the determination of the tissue that is not to be targeted.

6. The apparatus according to claim 5, wherein the ultrasound array is adapted to (control system 334, col. 34:45-57) set the range of azimuths responsive to the determination of the tissue that is not to be targeted.

7. The apparatus according to claim 5, wherein the detection functionality comprises an ultrasound transducer ("ultrasound probes" is synonymous to ultrasound transducer – see col. 16:54).

8. The apparatus according to claim 5, wherein the detection functionality comprises at least a portion of the ultrasound array ("ultrasound probes" is synonymous to ultrasound array – see col. 16:54).

9. The apparatus according to claim 5, wherein the detection functionality comprises imaging functionality (imaging disclosed in col. 3:53-57, col. 16:30-33, col. 16:53-56, and col. 34:51).

Sliwa discloses more than one transducer. See col. 7:15-17, *inter alia*.

*Sliwa is silent regarding azimuths and transducer numbers between 32 and 64.*

However, Shturman (5,331,947) discloses 32 and 64 transducers in an analogous catheter (note the similarities in catheter 20 in Shturman figures 7, 8, 9, 10, 11, 12, and 13 to those in Sliwa figures 5a-c, 12-13, 14a). Remember, the electrodes in Sliwa embodiments can seamlessly be exchanged for ultrasound transducers (Sliwa col. 3:7-10). See Shturman col. 6:47-52 where the number of transducers is suggestively 32 or 64 also known as “binary” numbers. The transducers are suggestively placed circumferentially, therefore capable of ablating between 180 and 359 degrees around the catheter.

Therefore, it would have been obvious at the time of the invention to modify Sliwa in view of Shturman by circumferentially placing 32 or 64 ultrasound transducers as done in Shturman on a Sliwa embodiment from figures 5a-c, 12-13, 14a. The motivation to include into the Sliwa embodiments 32 or 64 circumferentially placed transducers is to use a well-known strategy in ultrasound signal processing (binary number signal processing) and to be able to ablate all tissue surrounding the catheter (as suggested in the pulmonary vein treatment disclosed in Sliwa col. 3:10-15.)

**Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa (6,971,394) in view of Shturman (5,331,947) and further in view of Crowley et al. (6,004,269).**

*Sliwa/Shturman is silent regarding imaging transducers being adjacent to ablation transducers (making the image transducer part of the array) at the distal portion of the catheter and an external imaging transducer/detection functionality.*

Crowley discloses an analogous ultrasound catheter in which imaging transducers (416) are adjacent to ablation transducers (414) at the distal portion of the catheter. See figure 32a. Crowley also discloses an external visualizing ultrasound device in col. 29:35-37. The motivation to combine the patents is to better define what is suggested in Sliwa (the suggestion of ultrasound imaging) as well as to provide a specific means to visualize the targeted and non-targeted tissue.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Sliwa in view of Shturman and further in view of Crowley by using an external visualizing ultrasound device or an internal ultrasound transducer for visualizing at the distal tip of the catheter. Again, the motivation to combine the patents is to better define what is suggested in Sliwa/Shturman as well as to provide a specific means to visualize the targeted and non-targeted tissue. Sliwa suggests imaging as well as using transducers for purposes other than ablation in col. 3:53-57, col. 16:30-33, col. 16:53-56, col. 34:51, and col. 7:25-27.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
April 13, 2007



  
ROY D. GIBSON  
PRIMARY EXAMINER